

REMARKS

According to the Office Action of June 13, 2008, claims 16-22 and 25-30 are pending in the instant application, and have been rejected or objected to. Applicants submitted an Amendment on June 13, 2008. According to the Advisory Action of August 22, 2008, the Amendment was not entered. Now, Applicants amend the specification, Figure 7 and claims 16, 25 and 29. The specification and drawings have been amended to correct the reference number for the gauge in Figure 7. Claims 23 and 24 have been previously cancelled. No new matter has been added by these amendments.

The Office Action has objected to claims 25-27, has rejected all pending claims under 35 U.S.C. § 103, and has asserted a provisional non-statutory double patenting rejection against all pending claims. In view of the amendments and remarks, Applicants respectfully request that the rejections be reconsidered and withdrawn.

OBJECTION TO CLAIMS 25-27

Claims 25-27 have been objected to under 37 C.F.R. § 1.75(c) as being in improper dependent form. Particularly, the Office Action asserts that these claims do not further limit claim 16 because they only further limit the preamble.

Applicants respectfully traverse this objection because, in this case, the preamble, when read in the context of the entire claim, recites a limitation. "The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002)" (MPEP § 2111.02).

"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

(MPEP § 2111.02).

In this case, claim 16 recites “a gauge for use in a *surgical procedure* to determine *a first angle* in a first plane and a second angle in *a second plane*, said gauge comprising ...” (emphasis added). Surgical procedure is necessary to give life, meaning and vitality to the remainder of the claim because it limits the recited gauge to those used in surgical procedures, as opposed to any other type of gauge. Amended claim 25, which depends from claim 16, recites that “said surgical procedure is the insertion of an acetabular cup into a reamed acetabulum during hip replacement surgery, wherein the second connector is attached to the acetabular cup.” Since claim 25 further defines the surgical procedure and the second connector, it is a proper dependent claim.

Likewise, claims 26 and 27 further the first and second angle limitations. The first and second angle limitations breathe life, meaning and vitality to the plumb bob. Moreover, claim 16 recites “said first angle” and “said second angle” within the body of the claim. Accordingly, claims 26 and 27 are likewise proper dependent claims.

REJECTIONS UNDER 35 U.S.C. § 103

Rejection of Claims 16-22 and 25-28

Claims 16-22 and 25-28 have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,122,145 to Fishbane (hereinafter “Fishbane”) in view of U.S. Patent No. 2,385,424 to Shue *et al.* (hereinafter “Shue”).

The Claimed Invention

The invention, as recited in amended claim 16, is directed to a gauge for use in a surgical procedure to determine a first angle in a first plane and a second angle in a second plane. The gauge has a body, a plumb, a first connector and a second connector. The plumb bob is mounted to the body so as to hang under the influence of a local gravitational field. It is rotatable relative to the body in the first and second planes so as to determine the first and second angle respectively. The first connector is disposed on the body of the gauge. The second connector includes structure for attachment with a prosthetic component. Both connectors include corresponding structure for connection therebetween for mounting the gauge between the prosthetic component and a predefined site of a patient to allow

correlation between the predefined site of said patient and positioning of said prosthetic component.

The Cited References

Fishbane is directed to a measuring device that provides a leveling means (Fishbane at col. 1, lines 19-25). The leveling means is to ensure the proper positioning of the femur. Fishbane's leveling means is described as a small bubble level 10 (Fishbane at col. 2, lines 32-34). It is positioned on the top surface 50 of an interconnecting measuring member 8 (Fishbane at col. 3, lines 45-48). In practicing Fishbane's invention, "[t]he leg of the patient is moved, thereby moving the femur to center the bubble of the leveling device 10" (Fishbane at col. 3, lines 48-50). Thus, Fishbane's invention only ensures that the femur is level. The bubble is not capable of measuring the recited first and second angles because Fishbane does not teach a connector.

On page 2, the Office Action contends that Fishbane's acetabular guide 4 and femoral guide 6 are equivalent to the recited connector. The acetabular guide 4 comprises a bar 12 having a cylindrical pin guide 14 fixed at each end of the bar 12 (Fishbane at col. 2, lines 12-13). The pin guides 14 cooperate with the Steinmann pins 40 set in the ilium 42 above the acetabulum 43. The Steinmann pins 40 and the ilium 42 are not a prosthetic component.

Fishbane's femoral guide 6 likewise does not mount a gauge onto a prosthetic component. As the name implies, it mounts to a femur, particularly a Steinmann pin 44 set in the femur 46 (Fishbane at col. 3, lines 61-64).

The Office Action contends that Shue discloses a gauge wherein the level is a plumb bob mounted on a body and that the plumb bob hangs under the influence of gravity (Office Action at page 3).

Analysis

The Advisory Action contends that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim." However, the cited references do not teach a similar structure to those recited in the claims. The device, as depicted in Fishbane

Fig. 3, sits on top of pins implanted in the bone. Replacing Fishbane's bubble level with Shue's plumb bob level would still only allow one to level a femur. Moreover, the combination of Fishbane and Shue does not teach a first connector disposed on a body of a gauge. Nor does it teach or suggest a second connector that includes structure for attachment with a prosthetic component. Nor does it teach or suggest a gauge for mounting the gauge to a prosthetic component and a predefined site of a patient to allow correlation between the predefined site of the patient and positioning of the prosthetic component.

Furthermore, there has not been a reason provided why one would replace Fishbane's level with Shue's plumb bob. When making a rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). As part of a *prima facie* case, an examiner must establish some reason to combine the references. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 131 (2007); *Takeda Chemical Industries, Ltd. v. Alpharpharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007). The *KSR Int'l* Court acknowledged the importance identifying a reason that would have prompted a person of ordinary skill in the art to combine the elements in the way the claimed invention does. *KSR Int'l*, 127 S.Ct. at 1731; *Takeda Chemical*, 492 F.3d at 1356-1357. Repeatedly throughout the *KSR Int'l* decision, the Court discussed the importance that the result obtained by a particular combination was predictable to one of ordinary skill in the art. *KSR Int'l*, 127 S.Ct. at 1731 and 1739-1742.

In a recent case, the Board reversed an examiner's rejection for failing to provide the requisite reason to combine the references. *Ikeda*, App No. 08/352,079 at 7. The *Ikeda* application was directed to a method of removing hydrocarbons from exhaust gases. *Id.* at 2. In pertinent part, the claims recited an absorption catalyst B located downstream of a catalyst A in the direction of the exhaust gas. The claims were rejected as unpatentable under 35 U.S.C. § 103 in view of Swaroop, Abe and Patil. *Id.* at 3. Swaroop taught positioning the absorption catalyst B upstream catalyst A. *Id.* at 5. To remedy the deficiency in the art, the examiner cited "Patil and Abe as evidence of the 'coventionality of positioning the adsorbent catalyst 1 either upstream or downstream of a [three-way] catalyst 3' and thus conclude[d] that it would have been obvious to one of ordinary skill in this art to select an appropriate location for the adsorbent catalyst 16 in the apparatus of Swaroop" *Id.* at 5-6. The Board held that

The Examiner has failed to provide any cogent reason or technical discussion to support the conclusion that one of ordinary skill in this art would have employed the relative positions of the catalysts in Abe and Patil without the use of the other teachings of these references, namely an auxiliary heater and bypass lines with valving. Second, the Examiner has not explained why one of ordinary skill in this art would have used the teachings of Patil, requiring bypass lines and valving, when Swaroop specifically teaches away from the use of valving and bypass lines [citation omitted]. Third, the Examiner has not supplied convincing reasoning or technical discussion to support the proposed switch in relative position of the catalysts when Swaroop specifically teaches that the exhaust gas is "modified" by the adsorbent catalyst and this modified form of the exhaust gas is *then* sent to the main or three-way catalyst to undergo conversion to innocuous products [citation omitted]. ... Fourth, the Examiner has not explained why one of ordinary skill in this art would have proceeded contrary to the teachings of Patil, namely the teachings that "it is not possible merely to place zeolite 'in-line' in the exhaust system with the [main] catalyst has reached an effective temperature and unconverted hydrocarbons would still be discharged to the atmosphere" [citation omitted].

Ikeda, App. No. 08/352,079 at 7.

Likewise, in this case, the Office Action does not provide the requisite reason to substitute Fishbane's level with Shue's plumb bob. The Office Action contends that "[i]t would have been obvious ... to replace the spirit level of Fishbane with a plumb bob, as taught by Shue et al., in order to more accurately indicate an angular position with the use of a pointer and angle scale and in order to determine the angle with respect to two perpendicular axis, increasing the accuracy of the apparatus" (Office Action at page 4). However, in this case, the recited plumb bob serves as a means of measuring a first and second angle. The Office Action does not provide a reason why one would want to measure a first and second angle in the first place. Since Fishbane is directed to leveling the femur, the Office Action must provide some reason why one would measure a first and second angle instead of level the femur. Without such a reason, a *prima facie* case of obviousness has not been established.

For these reasons, Applicants respectfully request that the rejections asserted against claims 16-22 and 25-28 be reconsidered and withdrawn.

Rejection of claims 29 and 30

Claims 29 and 30 have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,314,432 to Paul (hereinafter "Paul") in view of U.S.

Patent No. 1,495,629 to Arthur (hereinafter "Arthur"). However, these references do not teach or suggest the recited connectors.

The Claimed Invention

Claim 29 is directed to a gauge for use in a surgical procedure to determine a first angle in a first plane and a second angle in a second plane. The gauge comprises a body, a first plumb bob is mounted to the body so as to hang under the influence of a local gravitational field. A second plumb bob is mounted to the body so as to hang under the influence of a local gravitational field. A first connector is disposed on the body of the gauge. The gauge also comprises a second connector, which includes structure for attachment with a prosthetic component. The first connector and the second connector include corresponding structure for connection therebetween for connection of the gauge between the prosthetic component and a predefined site of a patient.

The Cited References

On pages 4-5, the Office Action contends that Paul discloses a gauge 10 having a first level 26, a second level 27, and a connector 36. According to Paul, part 36 is a contact adhesive (Paul at col. 3, lines 60-61). Specifically, Paul states that "[i]n FIG. 4 peel strip 35 can be separated from contact adhesive 36 so that base plate 20 can be adhesively secured to skin surface when stereotactic device 10 is positioned over the spinal area of a prone patient."

On page 5, the Office Action contends that by replacing Paul's first and second levels with two copies of Arthur's plumb bob 19, the recited invention is reached.

Analysis

However, this combination lacks the connectors recited in amended claim 29. Paul's contact adhesive 36 adheres to the skin. Therefore, these references do not teach or suggest structure for attachment with a prosthetic component. Additionally, the references do not teach or suggest a first connector disposed on the body of the gauge. Nor do they teach or suggest a first connector and second connector including corresponding structure therebetween. Nor do they teach or suggest a gauge for connecting a prosthetic component

and a predefined site of patient to allow correlation between the predefined site and positioning of the prosthetic compound.

Furthermore, the Office Action does not provide the requisite reason to combine the references. Paul is directed to a lumbar spinal disc trocar placement device. In order to support a *prima facie* case of obviousness, the Office Action must establish a reason to substitute Paul's bubble levels with Arthur's plumb bob. The Office Action contends that this allows for more accurate measurement of an angular position (Office Action at page 5). However, Paul does not provide a reason to measure an angle. However, Paul is only concerned with leveling the x-axis and y-axis, not determining a first angle in a first plane and a second angle in a second plane. It is only concerned with ensuring that the trocar support is level in the x-axis and y-axis. Thus, in order to support a *prima facie* case, a reason for why one would not be concerned with measuring a first and second angle of a trocar support, instead of merely leveling it, must be provided.

Since such a reason has not been provided, a *prima facie* case of obviousness has not been established. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

PROVISIONAL DOUBLE PATENT REJECTION

Claims 16-22 and 25-30 have been provisionally rejected as purportedly unpatentable over claims 161-193 in co-pending U.S. App. No. 10/494,085 ("the co-pending '085 application") on the grounds of non-statutory double patenting. As of the date of this Amendment, claims 161-193 in the co-pending '085 Application have not been allowed. As such, Applicants are not required to address this provisional rejection at this time, and will address this provisional rejection if and when claims 161-193 in co-pending '085 Application are allowed.

On page 6, the Office Action contends that the double patenting rejection is proper and should be maintained. Since claims 161-193 in the co-pending '085 application have not yet been allowed, Applicants are not required to substantively respond to this provisional rejection at this time.

CONCLUSION

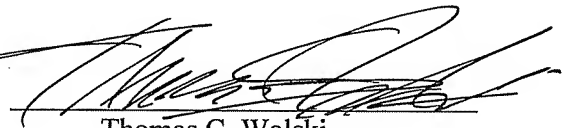
In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 16-22 and 25-30 in the instant application are novel and patentable over the prior art, and are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections, and allowance of these claims are respectfully requested.

Should the Examiner have any questions or concerns, the Examiner is invited to contact Applicants' undersigned attorney by telephone at 412-471-8815.

Respectfully submitted,

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